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PATENT
Attorney Docket No. AIB-09206

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Jeffrey Erickson

Serial No.: 10/505,191

Filed: 06/24/05

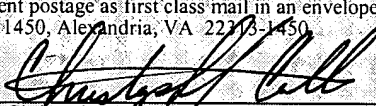
Entitled: Transgenic Production in Saliva

Group No.: 1632

Examiner: M. Sgagias

INFORMATION DISCLOSURE
STATEMENT TRANSMITTAL

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)	
I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
Dated: <u>March 21, 2007</u>	By: <u></u> Christopher J. Collins


Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in 37 C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: March 21, 2007



Peter G. Carroll
Registration No. 32,837

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Jeffrey Erickson
Serial No.: 10/505,191
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INFORMATION DISCLOSURE STATEMENT

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Dated: <u>March 21, 2007</u>	By:  Christopher J. Collins

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Patent No. 4,873,191 to Wagner *et al.*;
- U.S. Patent No. 5,175,384 to Krimpenfort *et al.*;
- U.S. Patent No. 5,445,958 to Feldman;
- U.S. Patent No. 5,476,777 to Holly *et al.*¹;
- U.S. Patent No. 5,565,350 to Kmiec;
- U.S. Patent No. 5,641,670 to Treco *et al.*;
- U.S. Patent No. 5,756,325 to Kmiec;
- U.S. Patent No. 5,811,279 to Kaetsu *et al.*;
- U.S. Patent No. 6,037,457 to Lord;
- U.S. Patent No. 6,140,552 to Deboer *et al.*;
- WO 91/12650 to Paratte *et al.*;
- WO 93/09222 to Selden *et al.*;

¹ U.S. Pat. No. 4,476,777 was cited incorrectly, the correct Patent Number is 5,476,777.

- Baum *et al.*, "In vivo gene transfer to salivary glands," *Critical Reviews in Oral Biology & Medicine* 10(3): 276-283, 1999;
- Beal, "The negative correlation between parotid salivary flow and sodium concentration during atropine infusion into conscious sodium-replete sheep," *Journal of Physiology*, 267(1): 19P-20P, 1977;
- Belitser *et al.*, *Biochim. et Biophys Acta* 154:367, 1968²;
- Binnie *et al.*, "Characterization of purified recombinant fibrinogen: partial phosphorylation of fibrinopeptide A," *Biochemistry* 32:107-113, 1993;
- Bishop, Martin J., Guide to Human Genome Computing, Academic Press, Harcourt Brace & Company Publishers, New York, 1994³;
- Bishop, M.J. and Rawings, C.J. Nucleic Acid and Protein Sequence Analysis: A Practical Approach, IRL Press, Oxford, UK, 1987⁴;
- Boskovic *et al.*, "Studies of the role of factor Va in the factor Xa-catalyzed activation of prothrombin, fragment 1'2-prethrombin-2, and dansyl-L-glutamyl-glycyl-L-arginine-meizothrombin in the absense of phospholipid," *J Biol Chem* 265(18): 10497-10505, 1990;
- Chin-Tih, *Biotechniques* 10(4):446-450, 1991⁵;
- Creighton, T.E. Protein Structure: A Practical Approach, IRL Press, Oxford, UK, 1989⁶;
- Degen, "The prothrombin gene and its liver-specific expression," *Seminars in Thrombosis and Hemostasis* 18(2): 230-242, 1992;
- Degen *et al.*, "Characterization of the cDNA coding for mouse prothrombin and localization of the gene on mouse chromosome 2," *DNA Cell Biol.* 9:487-498, 1990;
- Degen *et al.*, "Characterization of the complementary deoxyribonucleic acid and gene coding for human prothrombin," *Biochemistry* 22: 2087-2097, 1983;
- Dempfle *et al.*, "Purification of human plasma fibrinogen by chromatography on protamine-agarose," *Thromb Res* 46:19-27, 1987;

² Applicant's are attempting to obtain this reference and will provide copy once obtained.

³ This is a general references explaining methods performed without regard to any specific pages, therefore a copy is not supplied. If the examiner request a specific section from the reference, we will obtain a copy.

⁴ This is a general references explaining methods performed without regard to any specific pages, therefore a copy is not supplied. If the examiner request a specific section from the reference, we will obtain a copy.

⁵ Applicant's are attempting to obtain this reference and will provide copy once obtained.

⁶ This is a general references explaining methods performed without regard to any specific pages, therefore a copy is not supplied. If the examiner request a specific section from the reference, we will obtain a copy.

- Denman *et al.*, "Transgenic expression of a variant of human tissue-type plasminogen activator in goat milk. II: Purification and characterization of the recombinant enzyme," *Bio/Technology* 9: 839-843, 1991⁷;
- Doolittle, R.F., "Searching through sequence databases" *Met Enz* 183:99-110, 1990⁸;
- Ebert, "Gene transfer through embryo microinjection" *Animal Biotechnology* pp.233-250, 1989⁹;
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- Ebert, "A Moloney MLV somatotropin fusion gene produces biologically active somatotropin in a transgenic pig" *Mol. Endoc.* 2: 277-283, 1988¹¹;
- Ebert and Schindler, "Transgenic Farm Animals: Progress Report" *Theriogenology*, 39:121-135, 1993¹²;
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- Gunzel and Hoppe, *DTW-Dtsch-Tierarztl-Wochenschr* 83(9): 407-408, 1976¹⁶;
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- Haverkate *et al.*, "Fibrinogen milano II: a congenital dysfibrinogenaemia associated with juvenile arterial and venous thrombosis," *Thromb Homoeostasis* 55:131-135, 1986¹⁷;
- Heldebrandt *et al.*, "The activation of prothrombin," *J Biol Chem* 248(10): 3642-3652, 1973;
- Hogan *et al.*, Manipulating The Mouse Embryo, Cold Spring Harbor Press, Cold Spring Harbor, NY 1986¹⁸;
- Holm *et al.*, "Purification and characterization of 3 fibrinogens with different molecular weights obtained from normal human plasma," *Thromb Res* 37:165-176, 1985;
- Irwin *et al.*, "Identification of transgenic mice by PCR analysis of saliva," *Nature Biotechnology* 14(9): 1146-1148, 1996;
- Jorgensen *et al.*, *Circulation* 74 (Supp2): 1637 (abstract), 1986¹⁹;
- Koppert *et al.*, "A monoclonal antibody, specific for human fibrinogen, fibrinopeptide a-containing fragments and not reacting with free fibrinopeptide A," *Blood* 66:503, 1985;
- Kraemer *et al.*, Cold Spring Harbor Press, Cold Spring Harbor, NY, 1985²⁰;
- Krimpenfort *et al.*, *Bio/Technology* 9: 844, 1991²¹;
- Krishnaswamy *et al.*, "The prothrombinase-catalyzed activation of protherombin proceeds through the intermediate meizothrombin in an ordered, sequential reaction," *J Biol Chem.* 261(19): 8977-8984, 1986;
- Larson *et al.*, *Transgenic Research* 3(5):311-316, 1994²²;

¹⁶ Applicant's are attempting to obtain this reference and will provide copy once obtained.

¹⁷ The inventors name was incorrectly cited, as Hibernate, in the specification as filed. The correct name is Haverkate.

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- Linder *et al.*, *J Equine Vet Sci* 20(1): 52-54, 2000²³;
- Lorand, *Ann. N.Y. Acad Sci* 202(6), 1972²⁴;
- Lubon *et al.*, "Blood proteins from transgenic animal bioreactors," *Transfusion Medicine Reviews* X(2):131-141, 1996;
- Lutz *et al.*, "Techniques for collecting saliva from awake unrestrained, adult monkeys for cortisol assay," *American Journal of Primatology* 52(2):93-99, 2000;
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- Mihalyi, "Physicochemical studies of bovine fibrinogen. IV. Ultraviolet absorption and its relation to the structure of the molecule," *Biochemistry* 7:208-223, 1968²⁶;
- Meyers and Miller, "Optimal alignments in linear space" *Comput Applic in Biosci* 4: 11-17, 1988²⁷;
- Mikkelsen *et al.*, "Tissue-specific expression in the salivary glands of transgenic mice," *Nucleic Acids Research* 20(9): 2249-2255, 1992;
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²³ Applicant's are attempting to obtain this reference and will provide copy once obtained.

²⁴ Applicant's are attempting to obtain this reference and will provide copy once obtained.

²⁵ Applicant's are attempting to obtain this reference and will provide copy once obtained.

²⁶ The authors name was incorrectly cited as Mealy, in the specification as filed. The correct spelling is Mihalyi.

²⁷ Applicant's are attempting to obtain this reference and will provide copy once obtained.

- Phillips *et al.*, "A technique for saliva collection in dogs," *Laboratory Animal Science* 33(5): 465-466, 1983;
- Poulson *et al.*, "Coordination of murine parotid secretory protein and salivary amylase expression," *EMBO J* 5:1891-1896, 1986;
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- Sahlu *et al.*, *Canadian Journal of Animal Science* 72(2): 245-252, 1992²⁸;
- Sambrook *et al.*, Molecular Cloning: A Laboratory Manual, 2nd Ed., Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY, 1989²⁹;
- Seegers *et al.*, "Some properties of purified prothrombin and its activation with sodium citrate" *Blood* 5: 421-433, 1950;
- Seegers and Walz, eds. Prothrombin and other vitamin K proteins, Vols I (Ch. 8) and II (Ch. 7), CRC Press, Boca Raton, FL, 1986³⁰;
- Shaw and Schibler, "Structure and expression of the parotid secretory protein gene of mouse," *J Mol Biol* 192:567-576, 1986;
- Shiba *et al.*, *Amer J Physiol* 260, 1991³¹;
- Smith and Waterman, "Identification of common molecular subsequences," *J Mol Biol* 147: 195-197, 1981;
- Takebe *et al.*, "calcium ion-dependent monoclonal antibody against human fibrinogen: preparation, characterization, and application to fibrinogen purification," *Thromb Haemost* 73: 662-667, 1995;
- Tans *et al.*, "Meizothrombin formation during factor Xa-catalyzed prothrombin activation," *J Biol Chem* 266(32): 21864-21873, 1991;
- Tijburg *et al.*, "Formation of meizothrombin as intermediate in factor Xa-catalyzed prothrombin activation on endothelial cells," *J Biol Chem* 266(6): 4017-4022, 1991;

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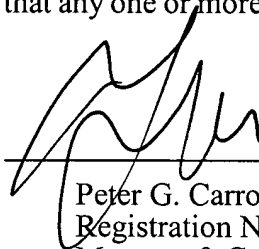
- Valenzuela *et al.*, *Amer J Pathol* 141:86, 1992³²;
- Walker *et al.*, "The activation of prothrombin by the prothrombinase complex," *J Biol Chem* 269(44): 27441-27450, 1994;
- Wright *et al.*, "High level expression of active human alpha-1-anti-trypsin in the milk of transgenic sheep" *Bio/Technology* 9: 830-834, 1991³³;
- Puhler, A. Ed. A. Genetic Engineering of Animals, VCH Publishers, New York, 1993³⁴;
- Murphy and D.A. Carter, eds., Methods in Molecular Biology: Transgenesis Techniques, Humana Press, Totwa, Volume 18, New Jersey, 1993³⁵;

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- Ting *et al.*, "Endogenous retroviral sequences are required for tissue-specific expression of a human salivary amylase gene," *Gene and Dev.* 6:1457-1465, 1992 discloses that the parotid-specific expression of amylase is dependent upon an endogenous retroviral sequence. The reference does not teach the collection of a protein of interest from saliva secreted at a level of at least 2 liters per day.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: March 21, 2007



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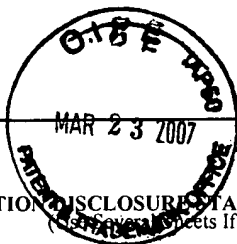
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FORM PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No. 3113-0226	Serial No.: 10/505,191			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)				Applicant: Erickson				
				Filing Date: 06/24/05				
(37 CFR § 1.98(b))				Group Art Unit: 1632				
U.S. PATENT DOCUMENTS								
Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date	
	1	4,873,191	10-10-89	Wagner <i>et al.</i>	800	25	8-18-86	
	2	5,175,384	12-29-92	Krimpenfort <i>et al.</i>	800	11	12-5-88	
	3	5,445,958	8-29-95	Feldman	435	214	2-23-93	
	4	5,476,777	12-19-95	Holly <i>et al.</i>	435	214	12-30-92	
	5	5,565,350	10-15-96	Kmiec	435	463	12-9-94	
	6	5,641,670	6-24-97	Treco <i>et al.</i>	435	325	5-13-94	
	7	5,756,325	5-26-98	Kmiec	435	463	9-9-96	
	8	5,811,279	9-22-98	Kaetsu <i>et al.</i>	435	214	8-1-97	
	9	6,037,457	3-14-00	Lord	530	413	1-31-97	
	10	6,140,552	10-31-00	Deboer <i>et al.</i>	800	15	6-7-95	
FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS								
		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	11	WO 91/12650	22.08.91	PCT	H02N 1	00		X
	12	WO 93/09222	13.05.93	PCT	C12N 5	10	X	
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	13	Baum <i>et al.</i> , "In vivo gene transfer to salivary glands," <i>Critical Reviews in Oral Biology & Medicine</i> 10(3): 276-283, 1999						
	14	Beal, "The negative correlation between parotid salivary flow and sodium concentration during atropine infusion into conscious sodium-replete sheep," <i>Journal of Physiology</i> , 267(1): 19P-20P, 1977						
	15	Binnie <i>et al.</i> , "Characterization of purified recombinant fibrinogen: partial phosphorylation of fibrinopeptide A," <i>Biochemistry</i> 32:107-113, 1993						
	16	Boskovic <i>et al.</i> , "Studies of the role of factor Va in the factor Xa-catalyzed activation of prothrombin, fragment 1'2-prethrombin-2, and dansyl-L-glutamyl-glycyl-L-arginine-meizothrombin in the absense of phospholipid," <i>J Biol Chem</i> 265(18): 10497-10505, 1990						
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	20	Dempfle <i>et al.</i> , "Purification of human plasma fibrinogen by chromatography on protamine-agarose," <i>Thromb Res</i> 46:19-27, 1987						
	21	Franza <i>et al.</i> , "Activation of human prothrombin by a procoagulant fraction from the venom of <i>echis carinatus</i> ," <i>J Biol Chem.</i> 250(17): 7057-7068, 1975						
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	23	Haverkate <i>et al.</i> , "Fibrinogen milano II: a congenital dysfibrinogenaemia associated with juvenile arterial and venous thrombosis," <i>Thromb Homoeostasis</i> 55:131-135, 1986						
	24	Heldebrandt <i>et al.</i> , "The activation of prothrombin," <i>J Biol Chem</i> 248(10): 3642-3652, 1973						
	25	Holm <i>et al.</i> , "Purification and characterization of 3 fibrinogens with different molecular weights obtained from normal human plasma," <i>Thromb Res</i> 37:165-176, 1985						
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Examiner:				Date Considered:				
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

FORM PTO-1449
(Modified)U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket No.: AIB-09206

Serial No.: 10/505,191

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Indicate pages, if necessary)

Applicant: Erickson

(37 CFR § 1.98(b))

Filing Date: 06/24/05

Group Art Unit: 1632

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

28	Krishnaswamy <i>et al.</i> , "The prothrombinase-catalyzed activation of prothrombin proceeds through the intermediate meizothrombin in an ordered, sequential reaction," <i>J Biol Chem.</i> 261(19): 8977-8984, 1986
29	Lubon <i>et al.</i> , "Blood proteins from transgenic animal bioreactors," <i>Transfusion Medicine Reviews</i> X(2):131-141, 1996
30	Lutz <i>et al.</i> , "Techniques for collecting saliva from awake unrestrained, adult monkeys for cortisol assay," <i>American Journal of Primatology</i> 52(2):93-99, 2000
31	MacGillivray <i>et al.</i> , "Recombinant genetic approaches to functional mapping of thrombin," <i>Ann N.Y. Acad Sci.</i> , 485:73-79, 1986
32	Mihalyi, "Physicochemical studies of bovine fibrinogen. IV. Ultraviolet absorption and its relation to the structure of the molecule," <i>Biochemistry</i> 7:208-223, 1968
33	Mikkelsen <i>et al.</i> , "Tissue-specific expression in the salivary glands of transgenic mice," <i>Nucleic Acids Research</i> 20(9): 2249-2255, 1992
34	Miller <i>et al.</i> , "Nonenzymic control of prothrombin activation," <i>Ann N.Y. Acad Sci</i> 370: 336-342, 1981
35	Miller, "The nonenzymic activation of prothrombin by polylysine," <i>J Biol Chem</i> 235: PC63-PC64, 1960
36	Mirels <i>et al.</i> , "Characterization of the rat salivary-gland B1-immunoreactive proteins," <i>Biochem. J.</i> 330: 437-444, 1998
37	Needleman and Wunsch, "A general method applicable to the search for similarities in amino acid sequence of two proteins," <i>J Mol Biol.</i> 48: 443-453, 1970
38	Ng <i>et al.</i> , "Quantifying thrombin-catalyzed release of fibrinopeptides from fibrinogen using high-performance liquid chromatography," <i>Methods Enzyme</i> 222: 341-358, 1993
39	Palmiter <i>et al.</i> , "Transgenic Mice," <i>Cell</i> 41: 343-345, 1985
40	Phillips <i>et al.</i> , "A technique for saliva collection in dogs," <i>Laboratory Animal Science</i> 33(5): 465-466, 1983
41	Poulson <i>et al.</i> , "Coordination of murine parotid secretory protein and salivary amylase expression," <i>EMBO J</i> 5:1891-1896, 1986
42	Rhee <i>et al.</i> , "Role of meizothrombin and meizothrombin-(des F1) in the conversion of prothrombin to thrombin by <i>echis carinatus</i> venom coagulant," <i>Biochemistry</i> 21: 3437-3443, 1982
43	Rosing <i>et al.</i> , "Formation of meizothrombin as intermediate in factor Xa-catalyzed prothrombin activation," <i>J. Biol. Chem.</i> 261(9): 4224-4228, 1986
44	Seegers <i>et al.</i> , "Some properties of purified prothrombin and its activation with sodium citrate" <i>Blood</i> 5: 421-433, 1950
45	Shaw and Schibler, "Structure and expression of the parotid secretory protein gene of mouse," <i>J Mol Biol</i> 192:567-576, 1986
46	Smith and Waterman, "Identification of common molecular subsequences," <i>J Mol Biol</i> 147: 195-197, 1981
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FORM PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No. AIB 0010	Serial No.: 10/505,191			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)				Applicant: Erickson				
(37 CFR § 1.98(b))				Filing Date: 06/28/05		Group Art Unit: 1632		
U.S. PATENT DOCUMENTS								
Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)				Applicant: Erickson	
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